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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,894	03/23/2001	Susan Michalowski	5051.401XXDV	7515

20792 7590 07/22/2002

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EXAMINER

SCHMIDT, MARY M

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 07/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/816,894

Applicant(s)

MICHALOWSKI ET AL.

Examiner

Mary Schmidt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-21, drawn to compositions comprising SEQ ID NO:1, classifiable in class 435, subclasses 410, 320.1; class 536, subclasses 23.1, 24.1; class 800, subclass 295.
 - II. Claims 1-21, drawn to compositions comprising SEQ ID NO:2, classifiable in class 435, subclasses 410, 320.1; class 536, subclasses 23.1, 24.1; class 800, subclass 295.
 - III. Claims 1-21, drawn to compositions comprising SEQ ID NO:4, classifiable in class 435, subclasses 410, 320.1; class 536, subclasses 23.1, 24.1; class 800, subclass 295.
 - IV. Claims 1-21, drawn to compositions comprising SEQ ID NO:5, classifiable in class 435, subclasses 410, 320.1; class 536, subclasses 23.1, 24.1; class 800, subclass 295.
 - V. Claims 1-21, drawn to compositions comprising SEQ ID NO:6, classifiable in class 435, subclasses 410, 320.1; class 536, subclasses 23.1, 24.1; class 800, subclass 295.

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- VI. Claims 1-21, drawn to compositions comprising SEQ ID NO:7, classifiable in class 435, subclasses 410, 320.1; class 536, subclasses 23.1, 24.1; class 800, subclass 295.
 - VII. Claims 1-21, drawn to compositions comprising SEQ ID NO:8, classifiable in class 435, subclasses 410, 320.1; class 536, subclasses 23.1, 24.1; class 800, subclass 295.
 - VIII. Claims 1-21, drawn to compositions comprising SEQ ID NO:9, classifiable in class 435, subclasses 410, 320.1; class 536, subclasses 23.1, 24.1; class 800, subclass 295.
 - IX. Claims 1-21, drawn to compositions comprising SEQ ID NO:10, classifiable in class 435, subclasses 410, 320.1; class 536, subclasses 23.1, 24.1; class 800, subclass 295.
 - X. Claims 1-21, drawn to compositions comprising SEQ ID NO:11, classifiable in class 435, subclasses 410, 320.1; class 536, subclasses 23.1, 24.1; class 800, subclass 295.
 - XI. Claims 1-21, drawn to compositions comprising SEQ ID NO:13, classifiable in class 435, subclasses 410, 320.1; class 536, subclasses 23.1, 24.1; class 800, subclass 295.
2. The inventions are distinct, each from the other because of the following reasons:

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Each of Groups I-XI are distinct from each other because each are drawn to compositions comprising patentably distinct nucleic acid sequences, SEQ ID NOS: 1, 2, 4, 5, 6, 7, 8, 9, 10, 11, and 13. MPEP 803.04 which states:

"Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq." Therefore, different genes having different gene sequences are capable of separate manufacture, use or sale, and are patentable (novel and unobvious) over each other, the nucleic acids in each of Groups I-XI are capable of separate manufacture, use or sale, and are patentable (novel and unobvious) over each other (though they may each be unpatentable because of the prior art) because of the unique nucleotide composition in each Group that renders the compositions in each Group distinct. Furthermore, it has been determined that 1(ONE) unique nucleic acid sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of 1(one) sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter, and the search required for each of Group I, II, III, IV, V, VI, VII, VIII, IX, X or XI is not required for the other Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Kay Pinkney*, whose telephone number is (703) 305-3553.

M. M. Schmidt
July 18, 2002

A handwritten signature in cursive script, appearing to read 'M. Schmidt', is located at the bottom right of the page.